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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,753	10/30/2001	Ken Fujise	UTSH:251US	6306

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,753

Applicant(s)

FUJISE ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 1-38, 48-62 (in full) and 68-83 (in part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-47 and 63-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/23/02 + 6/02</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Action is in response to the communication filed on 6/1/04. The amendment has been entered. Claims 1-83 are currently pending in the application and are addressed herein.

Election/Restrictions

Applicant's election without traverse of Group VI (claims 39-47 and new claims 63-83) in the reply filed on 6/1/04 is acknowledged.

Election was made **without** traverse in the reply filed on 6/1/04.

Specification

The specification is objected to because the specification contains sequences which require appropriate sequence identifiers (i.e., SEQ ID NOS). Specifically, see the sequences disclosed in Figure 1A, as well as the amino acid sequences disclosed on pages 139, 140 and 166 of the specification. With respect to the sequence disclosed in Figure 1A, it is acknowledged that the appropriate SEQ ID NOS. can be present in the description of the drawings; however, there are no sequence identifiers present in the instant description of figure 1A. It appears that the sequences disclosed in Figure 1A and on pages 139, 140 and 166 are not present on the instant Paper sequence listing. If the disclosed sequences are not present on the Paper sequence listing and the CRF, than submission of a new CRF and Paper sequence listing, as well as an amendment to the specification inserting the appropriate SEQ ID NO. is required. If the sequences disclosed are present on the CRF and paper sequence listing, then an amendment adding the appropriate SEQ ID NOS. to the specification is required.

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Additionally, the disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. For example, see page 24, line 16. All hyperlinks in the specification must be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 42 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because claim 43 recited the phrase “the modulator inhibits Fortilin activity by preventing its binding activity” (Emphasis Added). Here the word “its” renders the claims indefinite because it is unclear if “its” refers to the modulator or to Fortilin. It is noted that claim 43 depends from claims 42 and 39, thus claims 39 and 42 must encompass the limitations of claim 43. Therefore, claims 39, 42 and 43 are properly rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-47 and 63-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Written Description Guidelines for examination of patent applications indicates, “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus.” (See MPEP 2100-164)

In the instant case, the claims encompass methods for identifying modulators of “a Fortilin polypeptide” (see claims 39 and 68). The phrase “a Fortilin polypeptide” implies that there is more than one Fortilin polypeptide (see p. 10, lines 24-26). Looking to the specification for guidance, it is clear that term “a Fortilin polypeptide” encompasses variants of Fortilin, such as the possible variants described on pages 26-30 of the specification, including “biologically functional equivalents” of Fortilin which are described as variants of Fortilin that maintain the biological function of Fortilin (see p. 27, lines 15-20).

Therefore, the instant claims encompass methods wherein the methods utilize “a Fortilin polypeptide” wherein the Fortilin polypeptide could be any variant of Fortilin that maintains the

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biological activity of Fortilin. As such, the claims are drawn to the use of a molecule wherein the molecule can be any one species of huge genus of Fortilin variants. The specification has only described one species of this vast genus—the wild-type Fortilin polypeptide disclosed as SEQ ID NO:2. The specification does not disclose any other variants of Fortilin that maintain Fortilin activity, nor does the specification indicate which amino acids of Fortilin can be changed or deleted and result in a “biologically active” Fortilin variant. Furthermore, there is no structure function relationship described such that one of skill in the art would be able to clearly recognize any critical structural elements of Fortilin. Considering the huge number of possible variants encompassed by the claims and the limited guidance provided in the specification with respect to identifying the biologically active variants encompassed by the claims, it is the Examiner’s position that the specification has not adequately described a sufficient number of “representative species” encompassed by the claims, as required.

Additionally, claims 39-47 and 63-83 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, in view of the written description rejection above. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As mentioned above, the claims encompass Fortilin variants for which there is insufficient written description provided in the specification. Without a clear description of the biologically active Fortilin variants encompassed by the claims one of skill in the art would not know how to make or use the claimed invention without performing an undue amount of additional experimentation.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39, 40, 44, 63, 67, 68, 75-77 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by TESHIMA et al (Journ. of Immunol., 1998, cited in IDS).

The instant claims are drawn to a method for identifying a modulator of a Fortilin polypeptide comprising contacting the polypeptide with a candidate substance, and assaying whether the candidate substance modulates the Fortilin polypeptide (claim 39); wherein the assaying compares the activity of the Fortilin polypeptide in the presence and absence of the candidate substance (claim 40); wherein the modulator enhances Fortilin (claim 44); wherein the candidate substance is a polypeptide (claim 63); wherein the Fortilin polypeptide is in a cell (claim 67). As well as A method for identifying a modulator of a Fortilin polypeptide comprising: contacting a candidate modulator with a cell expressing the Fortilin polypeptide, measuring the level of Fortilin activity of expression or the cell, and, comparing the level of activity or expression of the cell to the level of Fortilin activity or expression of a cell not contacted with the candidate modulator, wherein a difference between the level of Fortilin activity or expression indicates that the candidate modulator is a modulator of a Fortilin polypeptide (claim 68); wherein the level of Fortilin expression is measured (claim 75); wherein the level of Fortilin polypeptide is measured (claim 76); wherein the level of Fortilin mRNA is measured (claim 77); wherein the candidate substance is a polypeptide (claim 79).

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TESHIMA teaches a method wherein they have identified GM-CSF, a polypeptide, as a modulator of the HRF. It is noted that the specification indicates the Fortilin is also known in the art as “Translationally Controlled Tumor Protein” (TCTP) which is encoded by TPT1 (see p. 17), and MACDONALD (CCG, 1999, cited in the IDS) teaches that TPT1 encodes HRF. Therefore, HRF is TCTP (as they are both encoded by TPT1), and thus HRF is Fortilin (as Fortilin is also known as TCTP). Therefore, TESHIMA teaches a method wherein they have identified GM-CSF, a polypeptide, as a modulator of the Fortilin (also known as HRF). Specifically, TESHIMA teaches that GM-CSF polypeptide (a cytokine) is added to macrophage cells that express HRF (Fortilin) resulting in the upregulation of expression of HRF mRNA and protein (e.g., see abstract, Figures 1-10). It is noted that method is performed in the presence and absence of GM-CSF and the results are compared, thus identifying GM-CSF polypeptide as a modulator of Fortilin (HRF).

Claims 39, 40, 44, 63, 66-69, 75, 77 and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by STURZENBAUM et al. (BBA, 1998, cited in IDS).

The instant claims are drawn to a method for identifying a modulator of a Fortilin polypeptide comprising contacting the polypeptide with a candidate substance, and assaying whether the candidate substance modulates the Fortilin polypeptide (claim 39); wherein the assaying compares the activity of the Fortilin polypeptide in the presence and absence of the candidate substance (claim 40); wherein the modulator enhances Fortilin (claim 44); wherein the candidate substance is a polypeptide (claim 63); wherein the candidate substance is a small molecule (claim 66); wherein the Fortilin polypeptide is in a cell (claim 67). As well as A

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method for identifying a modulator of a Fortilin polypeptide comprising: contacting a candidate modulator with a cell expressing the Fortilin polypeptide, measuring the level of Fortilin activity of expression or the cell, and, comparing the level of activity or expression of the cell to the level of Fortilin activity or expression of a cell not contacted with the candidate modulator, wherein a difference between the level of Fortilin activity or expression indicates that the candidate modulator is a modulator of a Fortilin polypeptide (claim 68); wherein the level of Fortilin activity is measured (claim 69); wherein the level of Fortilin expression is measured (claim 75); wherein the level of Fortilin mRNA is measured (claim 77); wherein the candidate substance is a small molecule (claim 83).

STURZENBAUM teaches a method wherein they have identified the heavy metal Cd, a small molecule, as a modulator of the TCTP. It is noted that the specification indicates the Fortilin is also known in the art as “Translationally Controlled Tumor Protein” (TCTP) which is encoded by TPT1 (see p. 17). Therefore, TCTP is Fortilin. As such, STURZENBAUM teaches a method wherein they have identified the heavy metal Cd, a small molecule, as a modulator of the Fortilin (also known as TCTP). Specifically, STURZENBAUM teaches that the small molecule Cd is added to soil as a pollutant, then the earth worm *lumbricus rubellus* is grown in the Cd polluted soil, thus adding the small molecule to a cell that expresses Fortilin.

STURZENBAUM teaches that the worms exposed to Cd have an increased expression of TCTP (Fortilin) (e.g., see abstract, Figures 3-6). It is noted that method is performed in the presence and absence of Cd and the results are compared, thus identifying the small molecule Cd as a modulator of Fortilin (TCTP).

Conclusion

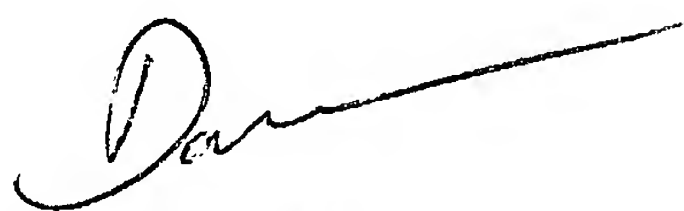
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
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DAVE T. NGUYEN
PRIMARY EXAMINER